Mitchell

MISSOURI BAPTIST MEDICAL CENTER

MB

3015 North Ballas Road
St. Louis, Missouri 63131
314/432-1212

FRED R. MILLS, FACHE
President & C.E.O.

January 21, 1994

Mr. Roy J. Caniano, Chief
U. S. Nuclear Regulatory Commission
Region III
Nuclear Materials Safety Branch
801 Warrenville Road
Lisle, IL 60532-4351

Re: Reply to a Notice of Violation

Dear Mr. Caniano,

This written response is in reply to your letter dated December 23, 1993, regarding the routine safety inspection conducted by Mark Mitchell, of your department, on November 16, 1993, of the activities authorized by our product material license number 24-11128-02.

Violation #1. The inspection findings indicate that we were in violation of license condition 15. Radioactive waste from an I^{131} procedure was stored on the roof which was not listed as a decay-in-storage area.

1) The roof was thought to be a designated storage area.

2) With verbal NRC approval from Mark Mitchell, the I^{131} waste was relocated on December 1, 1993, to the Cesium Room as a temporary decay-in-storage site.

3) The license will be amended to utilize the Cesium Room as a second decay-in-storage location.

4) Amendment will be sent by February 4, 1994.

Violation #2. The inspection findings indicate that we were in violation of 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a quality management program which must include written policies and procedures to meet the objective that prior to administration a written directive is prepared for any brachytherapy radiation dose.

1) As identified, a written directive was not signed and dated on the QMP form prior to the implantation. This was a violation of our procedures. A written directive indicating isotope, site and total dose was signed and dated in the progress notes of the therapy chart, instead of the QMP form, by the authorized user prior to the completion of the implantation for this same patient.

2) & 3) New Brachytherapy Survey forms have been implemented. All personnel involved with the brachytherapy procedures have been instructed in the importance of the authorized user signing and dating a written directive on the Brachytherapy Survey Form prior to implant. Personnel have also been instructed in the importance of the authorized user signing and dating a written directive on the Brachytherapy Survey Form indicating radioisotope treatment site and total dose (or total source strength and exposure time), before completion of therapy on the Brachytherapy Survey Form. The personnel preparing these sources have been reinstructed not to implant these sources without a written directive on the Brachytherapy Survey Form signed and dated by the authorized user. Enclosed are the copies of the new revised Department of Radiation Oncology Brachytherapy Survey Form.

4) Compliance was met December 14, 1993.

Violation #3. Inspection findings indicated that we were in violation of 10 CFR 35.32(c) requiring, in part, that the licensee evaluate and respond to each recordable event within 30 days after the discovery of the recordable event, and also retain a record for three years of the relevant facts and what corrective action, if any, has been taken.

1) A recordable event was not noted during the annual QMP audit. The reason is unknown -- the physicist performing the audit is no longer employed by this institution.

2) & 3) The corrective steps will be that the person performing the Annual QMP Audit for possible violations, including recordable events, will be a different individual who completed the survey form. All personnel involved with implementing the brachytherapy procedures or reviewing QMP records have been or will be reinstructed in the QMP procedures and importance of fully completing written directives. Any deviation from a complete written directive will be noted and identified as a recordable event.

4) The next quarterly review will be performed in March 1994.

We believe that these actions will bring us into compliance with NRC regulations. If you require any further information, please contact Tom Moenster, our Radiation Safety Officer, at (314)569-5535.

Sincerely,

Fred R. Mills, FACHE
President & C.E.O.

MISSOURI BAPTIST MEDICAL CENTER
St. Louis, MO

DEPARTMENT OF RADIATION ONCOLOGY
BRACHYTHERAPY SURVEY FORM (TEMPORARY)

Date: _____ Time: _____ Room #: _____

Patient Name: _____ Physician _____

Diagnosis: _____ Stage: _____

Area of Implant: _____ Radionuclide: _____

Type of Applicator: _____

Number or Sources/Ribbons: _____

Total Activity: _____

A. Intended Loading: Modified Loading:

Authorized User/Date: _____ _____

B. Sources Logged Out Of Source Storage Area
Proposed Loading in Accord with Prescription Sig: _____

C. Two Forms of Patient ID: Name Wrist band Birthdate SSN Family ID Other _____

D. Loaded as described?: Yes ____ No____ Authorized User/Date _____

E. Presciption: _____

Date/Time to Remove Implant: _____ Auth User/Date _____

Site	Dose (cGy) or mgRa-eq	Inserted		Removed		Reinserted		Removed		Total Time	Total dose
		Date	Time	Date	Time	Date	Time	Date	Time		

F. Treatment Plan/Calculations Reviewed and Verified _____
(Physicist)

G. Completed procedure agrees with written directive: _____
Authorized User/Date

Brachytherapy Room Survey:

	Location	mR/hr
A	Bedside with shield	
B	Bedside no shield	
C	1 m above applicator	
D	At wall at foot of bed	
E	At wall at right of bed	
F	At wall at left of bed	
G	At wall at head of bed	
H	Floor below bed	
J	Hall	
J	Other	
K	Other	

Instrument used: _____ Signs posted (Please check):

Chk source rdg: _____ Cal Date: _____ a. chart ( ) b. bed ( )

Person performing survey: _____ c. door ( ) d. wrist ( )

Adjacent rooms/corridor within limits of 2 mR/hr, 100 mR/yr to a patient? Yes No

DISCHARGE SURVEY (TEMPORARY IMPLANT):

(must be performed immediately after removing last implant)

Survey meter check source reading: _____

Measurement of patient: _____ mR/hr

Room survey: _____ mR/hr

Survey Instrument Used: Manufacturer: _____

Model: _____

Serial No.: _____

Calib. Date: _____

Person performing survey: _____

Time: _____ Date: _____

Person returning the sources and verifying the source count: _____